*भारतीय मानक*
***Indian Standard***

**IS 19022: 2023**

# चिकित्सीय वस्त्रादी — बैरियर फेस कवरिंग — विशिष्टि

# Medical Textiles — Barrier Face Covering — Specification

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Technical Textiles for Medtech Applications Sectional Committee, TXD 36

## FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the Technical Textiles for Medtech Applications Sectional Committee had been approved by the Textiles Division Council.

A barrier face covering is a non-medical mask, also called fabric mask, community mask or face covering, is neither a medical device nor personal protective equipment. The common uses of barrier face covering are as follows:

a) General population in public setting such as shops, shared workplaces, schools, worship places, restaurants, gyms, etc or in enclosed settings such as public transportation; and
b) For households, in indoor settings, when there is a visitor who is not a member of the household.

Barrier face covering are intended to be used to minimize the transmission of aerosol mediated disease transmission among general public. This standard has been formulated to address the performance of barrier face covering designed to protect others from exposure to wearer's respiratory droplets, saliva, sputum or respiratory secretions when talking, sneezing, coughing and breathing heavily.

This standard does not cover the requirement of surgical face masks which are meant for use at healthcare setting and a separate standard 'IS 16289 : 2014 Medical textiles — Surgical face mask — Specification' has been published on surgical face mask.

The composition of the Committee responsible for the formulation of this standard is listed in Annex D.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 2022 'Rules for rounding off numerical values (*second revision*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

*Indian Standard*

# MEDICAL TEXTILES — BARRIER FACE COVERING — SPECIFICATION

## 1 SCOPE

**1.1** This standard covers the minimum requirements for single use or reusable barrier face coverings intended for use by the general public to minimize the transmission of aerosol mediated disease particularly in epidemic or pandemic situations. Barrier face covering shall not be used by healthcare personnel and other people showing symptoms of viral or bacterial infection.

**1.2** Barrier face covering is not applicable for children below the age of 5 years due to chances of suffocation or overheating hazards.

## 2 REFERENCES

The standards listed in Annex A contain provisions, which through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated in Annex A.

## 3 TERMS AND DEFINITIONS

For the purposes of this standard, the following terms and definitions shall apply:

**3.1 Bacterial Aerosol —** A suspension of articles containing biological agents which have been dispersed in the gas.

**3.2 Barrier Face Covering —** Cloth based face covering that covers mouth, nose and chin with no gaps and with head or ear attachment and shall not incorporate any inhalation and/or exhalation valve(s). The barrier face covering is neither a medical device nor personal protective equipment, hence cannot be used by healthcare personnel.

**3.3 Differential Pressure/Delta P —** It is the pressure drop across a face covering under specific conditions of air flow, temperature and humidity. This is an indicator of the breathability of the face covering.

**3.4 Healthcare Personnel (HCP) —** Refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (for example blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These HCP may include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, students and trainees, contractual staff not employed by the health care facility, and persons (for example clerical, dietary, environmental services, laundry, security, maintenance, engineering and facilities management, administrative, billing, and volunteer personnel) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted among from HCP and patients.

**3.5 Manufacturer** — Natural or legal person with responsibility for the processing of raw material or inputs in any manner that results in the emergence of a new product having a distinct name, character and use.

**3.6 Particle Filtration Efficiency (PFE)** — It is the effectiveness of a material to filter aerosol droplets containing bacteria of a specified particle size range 3.0 µm. This is expressed as a percentage of a quantity that does not pass through the material.

## 4 MANUFACTURE AND WORKMANSHIP

**4.1** The barrier face covering shall be made from suitable textiles material that is not prohibited for use for the purpose under any applicable law/regulation in force so that the product made out of this meets the requirements specified in this standard.

**4.1.1** The fabric used for the manufacturing of barrier face covering shall be a single or multi-layered textile structure made of woven or non-woven (spunlace or spunbond or combination of spunbond and meltblown) or knitted structure.

NOTE — The manufacturer of the product should use sustainable materials to reduce the environmental impact.

The fabric used for manufacturing barrier face covering should not cause irritation to the user.

**4.2** The barrier face covering shall be clean and free from substances liable to cause tendering during storage. The product shall be free from sharp point, sharp edge, toxic and harmful substances. The general guidelines (for information only) for good manufacturing practice to maintain hygiene requirement at manufacturing facility are given in Annex C of IS 17514.

## 5 TYPES AND SIZE

**5.1** The barrier face covering has been classified in two categories: i) single use ii) reusable or multiple use.

**5.2** The size of barrier face covering shall be as per agreement between the buyer and the seller. The design of the product shall have proper fitting over the nose, mouth and chin of the wearer which shall ensures that the face covering fits closely to the face and allow normal activities and movement of head.

## 6 WASHING, DRYING AND HANDLING INSTRUCTION

The manufacturer shall provide the washing, drying, handling and storage instruction on every packet of reusable barrier face covering to ensure proper use and care by the consumer. Reusable barrier face coverings shall withstand at least 5 washing and drying cycles when tested at 40 °C using a normal wash procedure as specified in IS 15370.

## 7 GENERAL REQUIREMENTS

**7.1** The raw material/fabric used for manufacturing the reusable barrier face covering shall meet the following requirements (initially and after declared wash cycles) as specified in Table 1.

### 7.2 Flammability (Optional)

The barrier face covering shall not present a danger for the wearer and shall not be of highly flammable nature. The face piece shall not continue to burn after removal from the flame when tested in accordance with **A-5** of IS 9473.

## 8 FASTENING MECHANISM

The barrier face covering shall have suitable device for fastening the product for secure use for example, laces, elastic strips, fabric tie etc. or any other suitable material as agreed between buyer and seller. If adjustments to the fit are possible either by design or by using additional elements such as back of head clips, adjustment instructions shall be included in the instructions for use. The product shall meet the requirement of attachment strength as specified in Table 2. The material used for the fastening mechanisms shall not cause harm to skin and shall not be abrasive when the product is used.

## 9 PERFORMANCE REQUIREMENTS

**9.1** The barrier face covering shall meet the following requirements (initially and after declared wash cycles) as specified in Table 2.

## 10 MARKING

**10.1** Each piece of barrier face covering shall be legibly marked with the following information:

a) Name of the product;
b) Manufacturer’s name, initials or trade-mark, if any;
c) Month and year of manufacture or Batch/Lot No;
d) Type of face covering: single use or multiple use;
e) Size;
f) Use and care instructions;
g) Warning instruction on the product that’s this is neither a PPE nor a medical/surgical face mask;
h) Instruction for safe disposal of the product;
j) Declared life cycle/wash cycle;
k) Additional features of flammability (if applicable);
m) Country of origin; and
n) Any other statutory requirement as required by the law in force or as agreed between buyer and seller.

### 10.2 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the products may be marked with the Standard Mark.

## 11 SAMPLING AND CRITERIA FOR CONFORMITY

### 11.1 Lot

All he barrier face covering of the same material and size produced under similar conditions of manufacture shall constitute a lot.

### Table 1 Colour Fastness and Dimensional Stability Requirements of Raw Material/Fabric (Reusable Face Covering Only)

(*Clause* 7.1)

| Sl No. | Characteristic | Requirement | Method of Test, Ref to |
|---|---|---|---|
| (1) | (2) | (3) | (4) |
| i) | Colour fastness to rubbing: | | IS/ISO 105- X12 |
| | a) Dry | 4 or better | |
| | b) Wet | 4 or better | |
| ii) | Colour fastness to perspiration (acidic and alkaline): | | IS/ISO 105-E04 |
| | a) Colour Change | 4 or better | |
| | b) Staining | 4 or better | |
| iii) | Colour fastness to washing (A1S): | | IS/ISO 105-C06 |
| | Colour Change | 4 or better | |
| | Staining | 4 or better | |
| iv) | Dimensional stability to washing, percent, *Max* | | Annex C of IS 16394 |
| | (Length and width) | ± 3 | |

### Table 2 Performance Requirements for Barrier Face Covering

(*Clauses* 8 *and* 9.1)

| Sl No. | Characteristic | Requirement | Method of Tests |
|---|---|---|---|
| (1) | (2) | (3) | (4) |
| i) | Differential pressure, Pa/cm$^2$ | ≤ 60 | Annex B |
| ii) | Particulate filtration efficiency (at 3.0 µm), percent | ≥ 70 | Annex C |
| iii) | Tie and attachment strength, N, *Min* (apply axial tensile force for 10 s) | The sample shall not break before<br>Single use - 10<br>Multiple use -50 | IS 1969 (Part 2) |

**11.1.1** Each lot shall be tested separately for ascertaining the conformity of the lot.

**11.1.2** Unless otherwise sampling plan is specified in the contract or order, the number of barrier face covering to be selected from the lot shall depend on the size of the lot and shall be in accordance with column 2, 3 and 5 of Table 3.

**11.1.3** These barrier face coverings shall be selected at random from the lot. For this purpose, reference may be made to IS 4905.

**11.2 Number of Tests and Criteria for Conformity**

**11.2.1** All face coverings selected as per column 3 of Table 3 shall be examined for manufacture, workmanship and size (*see* **4** *and* **5**).

**11.2.1.1** Any face covering failing in one or more of the above requirements shall be termed as defective. The lot shall be considered as conforming to the above requirements, if the total number of defectives found in the sample is less than or equal to the acceptance number given in column **4** of Table 3. Otherwise, the lot shall be rejected.

**11.2.2** Out of the sample already found satisfactory according to **11.2.1.1**, a sub-sample as per column 5 of Table 3 shall be taken. This sub-sample shall be further tested for the remaining requirements.

**11.2.3** The lot shall be considered as conforming to the requirements of the specification, if the total number of defective face coverings found in the sample (*see* **11.2.2**) is less than or equal to the acceptance number as given in column 6 of Table 3.

## 12 PACKING

The barrier face coverings shall be packed securely so as to allow normal handling and transport without tearing and exposing the contents. Details of the packing shall be as agreed to between the buyer and the seller. Packaging of the product shall be such as to maintain the integrity of the product throughout its shelf life.

**Table 3 Number of Barrier Face Covering to be Selected**
(*Clauses* 11.1.2, 11.2.1, 11.2.1.1, 11.2.2 *and* 11.2.3)

| Sl No. | Lot Size | Non-Destructive Testing | | Destructive Testing | |
|---|---|---|---|---|---|
| | | **No. of Face Covering to be Selected** | **Acceptance Number** | **No. of Face Covering to be Selected** | **Acceptance Number** |
| (1) | (2) | (3) | (4) | (5) | (6) |
| i) | Up to 280 | 13[1] | 1 | 8 | 0 |
| ii) | 281 – 500 | 20 | 2 | 8 | 0 |
| iii) | 501 – 1200 | 32 | 3 | 13 | 0 |
| iv) | 1 201 – 3 200 | 50 | 5 | 13 | 0 |
| v) | 3 201 – 10 000 | 80 | 7 | 20 | 1 |

## ANNEX A

(*Clause* 2)

## LIST OF REFERRED STANDARDS

| *IS No.* | *Title* |
|---|---|
| IS 4905 : 2015 | Random sampling and randomization procedures (*first revision*) |
| IS 9473 : 2002 | Respiratory protective devices — Filtering half masks to protect against particles — Specification (*first revision*) |
| IS 16289 : 2014 | Medical textiles — Surgical face mask — Specification |
| IS 16394 : 2015 | Textiles — Woven shirting made of cotton, man-made fibres/filaments and their blend — Specification |
| IS 17514 : 2021 | Reusable sanitary pad/sanitary napkin/period panties — Specification |
| IS 1969 (Part 2) : 2018 /ISO 13934-2 : 2014 | Textiles — Tensile properties of fabric's: Part 2 Determination of maximum force using the grab method (*fourth revision*) |
| IS 15370 : 2020 /ISO 6330 : 2012 | Textiles — Domestic washing and drying procedures for textile testing (*first revision*) |
| IS/ISO 105-C06 :2010 | Textiles — Tests for colour fastness: Part C06 Colour fastness to domestic and commercial laundering (*first revision*) |
| IS/ISO 105-E04 : 2013 | Textiles — Tests for colour fastness: Part E04 Colour fastness to perspiration (*first revision*) |
| IS/ISO 105-X12 : 2016 | Textiles — Tests for colour fastness: Part X12 Colour fastness to rubbing (*first revision*) |

## ANNEX B

[(*Clause* 9.1, *Table* 2, *Sl No*. i)]

## METHOD FOR DETERMINATION OF BREATHABILITY (DIFFERENTIAL PRESSURE)

### B-1 PRINCIPLE

A device which measures the pressure differential required to draw air through a measured surface area at a constant air flow rate is used to measure the air exchange pressure of the face covering material, as shown in Fig.1. Water-filled manometers ($M_1$ and $M_2$) are used to measure the pressure differential. A flow meter is used for measurement of the air flow. An electric vacuum pump draws air through the apparatus and a needle valve is used to adjust the air flow rate.

### B-2 APPARATUS

**B-2.1 Flow Meter**, capable of measuring an air flow of 8 litre/min.

**B-2.2 Manometers**, M1 and M2.

**B-2.3 Electric Vacuum Pump**

**B-2.4 Valve**

### B-3 TEST SPECIMENS

Test specimens shall be complete face covering or shall be cut from face coverings. Each specimen shall be able to provide five different circular test areas of 2.5 cm in diameter. The number of specimens that shall be tested shall be five.

### B-4 PROCEDURE

**B-4.1** The test specimen is placed across the 2.5 cm diameter orifice (total area 4.9 cm2) and clamped into place so that the tested area of the specimen will be in line and across the flow of air.

**B-4.2** The pump is started and the flow of air adjusted to 8 litre/min.

**B-4.3** The manometers $M_1$ and $M_2$ are read and recorded.

**B-4.4** The procedure described in steps **B-4.1** through **B-4.3** is carried out on five different areas of the face covering and the readings averaged.

### B-5 CALCULATION OF DIFFERENTIAL PRESSURE

For each test specimen, calculate the differential pressure, $\Delta P$ as follows:

$$\Delta P = (Xm_1 - Xm_2) / 4.9$$

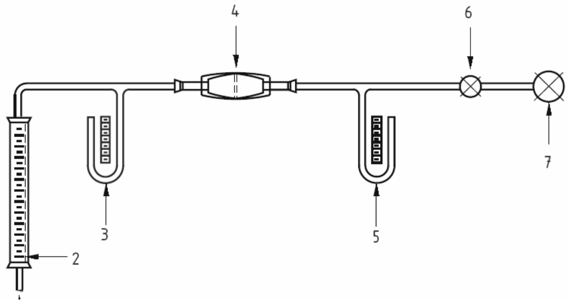
where

$Xm_1$ = water pressure, in mm, manometer 1, mean of five test areas, low pressure side of the material;

$Xm_2$ = water pressure, in mm, manometer 2, mean of five test areas, high pressure side of the material;

4.9 = area of the test material, in $cm^2$; and

$\Delta P$ = pressure differential per $cm^2$ of test material expressed as mm of water.



1 Air inlet
2 Flow meter
3 Manometer $M_1$
4 Filter material
5 Monometer $M_2$
6 Valve
7 Vacuum pump

FIG. 1 APPARATUS FOR MEASURING AIR RESISTANCE

## B-6 TEST REPORT

The test report shall include the following information:

a) Flow rate during testing; and
b) Differential pressure for each test specimen.

# ANNEX C

[(*Clause* 9.1, *Table* 2, *Sl No*. ii)]

# METHOD FOR DETERMINATION OF PARTICULATE FILTERATION EFFICIENCY

## C-1 PRINCIPLE

Filtered and dry air is passed through an atomizer to produce an aerosol containing suspended latex spheres. This aerosol is then passed through a charge neutralizer. The aerosol is then mixed and diluted with additional pre-conditioned air to produce a stable, neutralized and dried aerosol of latex spheres to be used in the efficiency test.

## C-2 APPARATUS

Aerosol test system consisting of clean, dry compressed air supply, high-efficiency particulate air (HEPA) filters, aerosol generator capable to generate aerosol size of 3.0 microns, charge neutralizer, humidifier, test filter holder and duct assembly, pressure drop measuring device, air flow rate measuring device, temperature and humidity detectors and optical particle counters.

## C-3 TEST SPECIMEN

**C-3.1** Prior to test, the specimens shall be conditioned to moisture equilibrium in the standard atmosphere of temperature 27 °C ± 2 °C and relative humidity of 65 percent ± 2 percent. When the test specimens have been exposed to standard atmosphere for at least 6 h in such a way to expose as far as possible, all portions of the specimens to the atmosphere, they shall be deemed to have reached moisture equilibrium.

## C-4 TEST PROCEDURE

**C-4.1** Set main airflow, dilution airflow and aerosol generator airflow to test conditions. Establish airflow controls at required test face velocities as to have air dilution (drying) for aerosol generation of 2 : 1 or greater. Purge main airflow for 10 min to 15 min. Warm up optical particle counter (OPC) for 15 min to 30 min. After OPC warm up, check built in calibration signal or OPC output signal on an oscilloscope for stable gain on photo-multiplier tube or other optical detectors. Switch the OPC into main airflow and balance OPC airflow against the main airflow. Observe OPC count data.

**C-4.2** Set-up the aerosol generator with a nominal volume of the distilled water to be used in the latex dilutions (preferably 1 : 1 000 or 1 : 10 000) capable of generating 10 000 to 15 000 particles at 28.3 litre per minute (LPM). Without a material specimen in the test system, establish the main system airflow and the OPC sampling airflow for the upstream sampling probe. Sample the upstream and downstream airflow for 1 min each. Verify complete drying of the aerosol droplets by comparing these counts to count obtained in **C-4.1**. Run this drying test for 1 h, sampling every 15 min for upstream and downstream counting and record aerosol stability and system relative humidity. Measure the water consumption of the aerosol generator. Record any dilution airflow and the required air pressure for the aerosol generator.

**C-4.3** Fill the aerosol generator with the desired dilution of latex suspension. Without a filter media sample in the test specimen, close the system and establish the required system airflows. Stabilize the system airflow with the aerosol suspension for approximately 5 min, then begin successive 1 min upstream and downstream counts for 15 min or until reproducible counts are established. Verify that counting is within a 10 percent coincidence of the OPC.

**C-4.4** Install the material specimen in the test system and re-establish the required airflows. Monitor the OPC airflow and adjust for the added material specimen on the sample flow. Sample and record the upstream and downstream aerosol counts for a minimum of 5 counts at each position using a 1 min sampling time. If the downstream count is less than 100, extend the test until 100 counts are obtained. However do not count longer than 5 min to avoid the loading the specimen.

**C-4.5** Monitor the upstream counts; if these counts fall outside 100 percent ± 1 percent penetration average with a coefficient of variation of 3 percent, stop the test and check the system for aerosol generation instability.

## C-5 CALCULATION

Average the upstream counts and the downstream counts, then calculate the decimal efficiency by the following definition:

$$\text{Efficiency} = 1 - \frac{(\text{average downstream counts})}{(\text{average upstream counts})}$$

## ANNEX D

(*Foreword*)

## COMMITTEE COMPOSITION

Technical Textiles for Medtech Applications, TXD 36

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## Amendments Issued Since Publication

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